

Douglas, Amy

From: Jo Gambell
Sent: 23 April 2012 11:47
To: 'fredric.steinberg@mhra.gsi.gov.uk'
Cc: 'clintrialhelpline@mhra.gsi.gov.uk'; UKALL14
Subject: 2009-012717-22 Urgent Safety Measure

Dear Dr Steinberg

Please find a summary below of the information discussed over the phone in reference to the Urgent Safety Measure.

We held a UKALL14 Trial Management Group meeting on Friday 20th April. We have reviewed the current data and have noted with concern the relatively high phase 1 induction morbidity and mortality in UKALL14 by comparison with UKALL12.

The median age of patients in UKALL14 is considerably higher than that in UKALL12 and the excess toxicity is mostly apparent in older individuals. As a result, the TMG has made recommendations for amendments to the trial protocol.

SUMMARY OF CHANGES TO THE TRIAL PROTOCOL

For all patients, irrespective of Philadelphia status

The Daunorubicin doses will be halved; namely 30mg/m² will be given instead of 60mg/m² on the same time schedule as presently

For patients with Philadelphia negative ALL over 40 years of age

The first dose (day 4) of pegylated asparaginase during Induction 1 will be omitted. Pegylated asparaginase will be given only once during induction phase 1, on day 18

For patients with Philadelphia positive ALL only

NO pegylated asparaginase at all will be given during induction.

Please let me know if you require any further information

Thanks

Jo

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